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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,422	12/27/2005	Tina Rademacher	RO4126US (#90568)	3869

28672 7590 09/30/2009
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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
09/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,422	RADEMACHER ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 - 6, 8 - 36* is/are pending in the application.

4a) Of the above claim(s) *15 - 19, 30 - 32, 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3 - 6, 8 - 14, 20 - 29, 33 - 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 19, 2009 has been entered.

Applicants' arguments, filed June 19, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. None of the cellulose derivatives other than those listed in claim 20 and none of the starch derivatives meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the full genus of celluloses derivatives other than those explicitly listed and starch derivatives encompassed by the claim, since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a derivative of either starch or cellulose.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3 – 6, 8 – 14, 20 – 29 and 33 – 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Line 11 of claim 11 recites "said pH being". It is unclear whether "said pH" refers to the pH value of the base

mass (line 9) or the physiological pH of the mucosa to which the administration form is to be applied (lines 10 – 11). Please clarify.

6. Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 depends from cancelled claim 7, and claim 25 depends from claim 24. Therefore, the complete set of limitations present in the claims cannot be determined. For the purposes of applying art below, based on the previous set of claims, these claims are being interpreted as further limiting the range of pH values (for either the base mass of the physiological pH of the mucosa to which the administration form is to be applied, see rejection above) present in claim 1. Clarification is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3 – 5, 8 – 11, 13, 21, 22, 24 – 26 and 29 were rejected under 35 U.S.C. 102(b) as being anticipated by Kigasawa et al. (US 4,572,832). This rejection is

MAINTAINED for the reasons of record set forth in the Office Action mailed February 17, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Kigasawa does not teach all of the claim limitations. The amended claims recite the specific pH value that is required depending on the target mucosa to which the administration form is applied. The assertion by the Examiner that the pH of the final composition is approximated or adapted to the physiological values of the mucosa is merely speculative without intentional adjustment of the pH and it cannot be assumed or predicted that the pH of the final composition will correspond to the physiological pH of the target mucosa in each case. The soft buccals of example 8(b) were adjusted to pH 6.5, which is not suitable for the administration to herbivore such as a rabbit mucosa. Also in regards to this example, which is the only example that discusses a specific pH value, the only matrix polymer that is present is gelatin, which is excluded from the list of matrix polymers in claim 3. Kigasawa et al. also fails to teach that the pH of the described soft buccals should be adjusted differently depending on type of mucosa the soft buccal will be administer to.

These arguments are unpersuasive. The claims under examination are composition claims and the specific site of administration (e.g., human oral, nasal or vaginal mucosa; oral mucosa of an herbivore) is a recitation of intended use. As discussed previously, the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

capable of performing the intended use, then it meets the claim. Applicant have also amended claim 1 to reflect specific pH values that are approximated or adapted to the physiological pH values of the mucosa to which the administration form is to be applied. These pH values now define a range of pH values for the base mass, this range being from about 4 to 9. Therefore, the prior art does not need to teach that for the intended use of oral mucosa of human the pH should be between 5.5 and 6.5, but rather that the pH of a base mass comprising at least one matrix forming polymer and at least one active substance has a pH of between about 4 and 9, that is pH values which are capable of being applied to the oral mucosa of a herbivore or the oral, nasal or vaginal mucosa of a human. Applicants have not presented any evidence showing that the base mass produced by Kigasawa et al. does not have a pH that falls within this range. Arguments without factual support are mere allegations and are not found to be persuasive. The one example of Kigasawa that explicitly mentions pH has a pH of 6.5, which falls squarely within the range being claimed. While this example does not use a matrix-forming polymer recited in claim 3, example 8(a) uses gelatin, which is recited in claim 3 and there is no evidence that the pH of the base mass does not fall between about 4 and 9.

9. Claims 1, 3 – 5, 9 – 11, 13, 14, 20, 22, 24, 25, 27 – 29, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al. (US 4,764,378).

Keith et al. discloses buccal dosage forms for transmucosal administration of drugs (abstract) and thus the pH of the base mass of these dosage forms is

approximated or adapted to the physiological values of the mucosa to which the administration form is to be applied. The base mass comprises PEG (polyethylene oxide) of varying molecular weights (100, 1450, 3350 and 8000); propylene glycol, a plasticizer (col 4, ln 31 - 33); and polyvinylpyrrolidone that when cut in a film, dissolves in less than 60 seconds when placed in the buccal pouch or sublingually (Example 1, col 6, ln 15 – 43). In example 2, the base mass contains 5% of the plasticizer propylene glycol (col 6, ln 46 – 57). A variety of pharmaceutical active ingredients can be incorporated in the base material, including 5% verapamil hydrochloride (column 7, ln 1 – 6), a hydrochloride salt form of the active ingredient, resulting in a final formulation in which the polymer portion would be less than 95% (5% active ingredient, 3% propylene glycol).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 3 – 6, 8 – 11, 13, 14, 20 – 29 and 33 – 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al. (US 4,572,832). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed February 17, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds discussed above when this reference was applied under 35 USC 102(b). As Kigasawa et al. fails to teach pH adjustment to the specified range depending on the mucosa the form will be applied to, the Examiner's rationale previously set forth is no longer germane. In regards to claims 33 and 34, the example in which Kigasawa et al. uses the salt form of the drug is not the same example in which the pH of the base mass was adjusted, which uses pindolol as the active ingredient.

These arguments are unpersuasive. As discussed in greater detail above, the instant claims only require that the pH of the base mass be approximated or adapted to the range recited for the pH values of various physiologic mucosa. Applicants have not presented any evidence that the pH values of the formulation in which the pH was explicitly adjusted or any of the other examples in which the pH did not need to be adjusted does not meet this limitation of the claims. Therefore, the rationale as set forth previously is still germane and this rejection is maintained.

14. Claims 1, 3 – 6, 8 – 11, 13, 14, 20 – 29 and 33 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al. as applied to claims 1, 3 – 6, 8 – 11, 13, 14, 20 – 29 and 33 – 35 above, and further in view of Lydzinski et al. (US 2003/0099691).

As discussed in previous Office Actions in greater detail, Kigasawa et al. discloses soft buccal compositions which comprise a medicament to be absorbed through the oral cavity, a water-soluble protein, a polyhydric alcohol and a fatty acid ester and/or a carboxyvinyl polymer (col 1, ln 36 – 49). Kigasawa et al. discloses that additives can be added in addition to the required ingredients, including flavorings (aroma substances) such as menthol, lemon oil and citrus flavor as well as other excipients, disintegrating adjusting agents, emulsifiers, dispersants, binders and thickeners (col 5, ln 56 – col 6, ln 6).

Kigasawa et al. does not explicitly disclose a formulation wherein the active substance is one or more aroma substances without a pharmaceutical active substance being included in the administration form.

Lydzinski et al. discloses am oral film that useful for delivering an agent to an animal or human to produce either a therapeutic or cosmetic effect, such as breath fresheners or fragrances (¶ [0006]), both of which read on the aroma substance of the instant claims. The active agent can be used in any amount desired, the only limitation being the potential load of the film, but generally, the amounts used will range from about 0.5% to about 15%, with substantially higher amounts for breath fresheners than for pharmaceutical agents (¶ [0024]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate an aroma substance in place of the pharmaceutically active ingredient in the compositions of Kigasawa et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because the inclusion of an aroma substance (breathe freshener or fragrance) results in an oral film that quickly disintegrates in the mouth, leaving the user with fresh or scented breath.

The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each

ingredient to add in order to best achieve the desired results. As Lydzinski et al. teaches, almost any amount of active substance can be present in the film and the type of active ingredient will determine how much is added, with pharmaceutically active substances generally be present in lower amounts than breath freshener ingredients, one would determine the optimal amount to add based on the particular active ingredient that is used.

15. Claims 1, 3 – 6, 8 – 14, 20 – 29, 33 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al. further in view of Rault et al. (US 5,900,247). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed February 17, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds that Rault is referred to simply for teaching a multilayered dosage form and clearly does not make up for any of the aforementioned deficiencies of Kigasawa.

This argument is unpersuasive. As discussed in greater detail above, Kigasawa et al. does teach all of the limitations of the instant claims and therefore Rault et al. is not required to cure these deficiencies.

16. Claims 1, 3 – 5, 9 – 11, 13, 14, 20 – 22, 24, 25, 27 – 29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378).

Keith et al. discloses buccal dosage forms for transmucosal administration of drugs (abstract) and thus the pH of the base mass of these dosage forms is

approximated or adapted to the physiological values of the mucosa to which the administration form is to be applied. The matrix comprises about 20% to about 75% of a low molecular PEG (col 3, ln 16 – 24), about 2% to about 60% of a medium to high molecular weight PEG (col 3, ln 42 – 46), about 1% to about 40% of a high molecular PEG (col 3, ln 61 – 68), about 25% to about 40% of an auxiliary polymeric ingredient such as polyvinylpyrrolidone (col 4, ln 13 – 16), minor amounts of additional ingredients such as up to about 5% of plasticizer (col 4, ln 28 – 33) and between about 0.01% and about 10% of active ingredient (col 5, ln 40 – 42). The base mass comprises PEG (polyethylene oxide) of varying molecular weights (100, 1450, 3350 and 8000); propylene glycol, a plasticizer (col 4, ln 31 - 33); and polyvinylpyrrolidone that when cut in a film, dissolves in less than 60 seconds when placed in the buccal pouch or sublingually (Example 1, col 6, ln 15 – 43). In example 2, the base mass contains 5% of the plasticizer propylene glycol (col 6, ln 46 – 57). A variety of pharmaceutical active ingredients can be incorporated in the base material, including 5% verapamil hydrochloride (column 7, ln 1 – 6), a hydrochloride salt form of the active ingredient, resulting in a final formulation in which the polymer portion would be less than 95% (5% active ingredient, 3% propylene glycol). One formulation contained 10% by weight of the active ingredient verapamil free base (col 7, ln 38 – 42).

Keith et al. does not explicitly disclose an administration form wherein the polymer portion ranges between 15% and 75%.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to vary the amounts of polymer matrix, active ingredients and

additional ingredients in the buccal dosage form. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. The amount of plasticizer or various polymer ingredients will alter the physical properties of the produced mass, such as the melting point, crystalline character and disintegration time (col 3, ln 46 - 56; col 4, ln 13 - 18). The amount of active ingredient included in the dosage form will depend on, for example, the therapeutic dose required for the particular active ingredient, the condition being treated, the physical condition (e.g., overall health, age, weight) of the patient being treated and the desired dosing schedule (col 5, ln 37 – 65).

17. Claims 1, 3 – 5, 9 – 14, 20 – 22, 24, 25, 27 – 29, 33 and 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. as applied to claims 1, 3 – 5, 9 – 11, 13, 14, 20 – 22, 24, 25, 27 – 29, 33 and 34 above, and further in view of Rault et al. (US 5,900,247).

As discussed in greater detail above, Keith et al. discloses buccal dosage forms containing up to 10% by weight active ingredient, in a matrix-forming polymer mass.

Keith et al. does not disclose a multi-layer dosage form.

Rault et al. discloses a bioadhesive pharmaceutical composition to locally release active ingredients through various mucosal membranes (col 1, ln 7 – 15). The bioadhesive composition comprises a vinyl acetate/polyvinylpyrrolidinone copolymer, at least one active ingredient, optionally a cellulose or cellulose derivative such as ethyl cellulose or hydroxypropylmethyl cellulose and excipients such as plasticizers flavoring agents or sweeteners. After spreading of the bioadhesive mixture onto a biodegradable or non-biodegradable protective film or substrate, the assembly is dried (col 2, ln 54 - 62). The protective film is chosen for its adhesive or bioadhesive properties and is peelable (col 2, ln 63 – 65). This process results in the production of a multilayered administration form.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a buccal administration form as taught by Keith et al. and to place this material on a protective film, as taught by Rault et al., resulting in a multilayered administration form. The person of ordinary skill in the art would have been motivated to make those modifications to provide the dosage form with a protection layer and reasonably would have expected success because the bioadhesive mixture of Rault et al. and the matrix of Keith et al. have the same or similar components used for the same purposes, namely the delivery of pharmaceutical agents from the matrix.

18. Claims 1, 3 – 5, 8 – 11, 13, 14, 20 – 22, 24, 25, 27 – 29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. as applied to claims 1, 3

– 5, 9 – 11, 13, 14, 20 – 22, 24, 25, 27 – 29, 33 and 34 above, and further in view of Bergeron et al. (WO 99/53897) and Gibson et al. (EP 0386960).

As discussed in greater detail above, Keith et al. discloses buccal dosage forms containing up to 10% by weight active ingredient, in a matrix-forming polymer mass.

Keith et al. does not disclose the presence of an agent that alters the pH from the Markush group of claim 8.

Bergeron et al. discloses a formulation of film-forming ingredient and an active agent for topical formulations (p 1, ln 8 – 9). The pH of the formulation can be adjusted to meet the requirements of the target tissue (p 13, ln 31 – 33). For formulations applied to the vaginal mucosa, a pH of about 4.0 – 4.5 should be used (p 13, ln 33 – 34).

Bergeron et al. does not disclose any agents that would adjust the pH depending on the target tissue.

Gibson et al. discloses that the pH of the compositions can be adjusted through the use of pharmaceutically acceptable acids or bases such as sodium or hydrochloric acid and that pH can be maintained by the use of buffering agents (p 9, ln 34 – 43).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a pH adjusting agent in the compositions of Keith et al. The person of ordinary skill in the art would have been motivated to make those modifications, and reasonably would have expected success because Bergeron et al. discloses that the pH of the formulations should be adjusted to meet the requirements of the target tissue and Gibson et al. discloses that one way to adjust the pH is through the use of compounds such as buffer, sodium hydroxide and/or hydrochloric acid.

Determining the appropriate pH and using acids, bases and/or buffers to provide a composition with that pH is within the skill of one of ordinary skill in the art.

19. Claims 1, 3 – 5, 9 – 11, 13, 14, 20 – 22, 24, 25, 27 – 29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. as applied to claims 1, 3 – 5, 9 – 11, 13, 14, 20 – 22, 24, 25, 27 – 29, 33 and 34 above, and further in view of Lydzinski et al. (US 2003/0099691).

As discussed in greater detail above, Keith et al. discloses buccal dosage forms containing up to 10% by weight active ingredient, in a matrix-forming polymer mass. The active ingredients are pharmaceutically active compounds like scopolamine or verapamil hydrochloride.

Keith et al. does not disclose a formulation wherein the active substance is one or more aroma substances without a pharmaceutical active substance being included in the administration form.

Lydzinski et al. discloses am oral film that useful for delivering an agent to an animal or human to produce either a therapeutic or cosmetic effect, such as breath fresheners or fragrances (¶ [0006]), both of which read on the aroma substance of the instant claims. The active agent can be used in any amount desires, the only limitation being the potential load of the film, but generally, the amounts used will range from about 0.5% to about 15%, with substantially higher amounts for breath fresheners than for pharmaceutical agents (¶ [0024]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate an aroma substance in place of the, pharmaceutically active ingredient in the compositions of Keith et al.. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because the inclusion of an aroma substance (breathe freshener or fragrance) would results in an oral film that quickly disintegrates in the mouth, leaving the user with fresh or scented breath. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. As Lydzinski et al. teaches, almost any amount of active substance can be present in the film and the type of active ingredient will determine how much is added, with pharmaceutically active substances generally be present in lower amounts than breath freshener ingredients, one would determine the optimal amount to add based on the particular active ingredient that is used.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW